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Appl. No.	:	10/692,083	Confirmation No.:	8282
Applicant	:	William Martin Belef		
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Title	:	Methods for Treating Spinal Discs		
Group Art Unit	:	3738		
Examiner	:	Suba Ganesan		
Docket No.	:	15457.4016		
Customer No.	:	34313		

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APPEAL BRIEF AND REQUEST FOR ORAL HEARING

Sir:

Real Party in Interest

Gateway Medical, Inc. Inc. is the real party in interest.

Related Appeals and Interferences

There are no related appeals of interferences.

Status of Claims

Claims 1-33 are pending in this application and all of these claims stand rejected.

CERTIFICATE OF MAILING
37 CFR §1.8

I hereby certify, pursuant to 37 CFR §1.8, that I have reasonable basis to expect that that this paper or fee (along with any referred to as being attached or enclosed) is being electronically transmitted to the U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22315-1450.

Dated: October 24, 2007

Lynne Fulmer

Lynne Fulmer

Status of Amendments

All amendments which have been filed have been entered.

Summary of Claimed Subject Matter

There are three independent claims, which are claims 1, 15 and 27. These claims are directed to a method comprising, as recited in claim 1, creating an opening in the annulus fibrosis of a spinal disc, performing a procedure within the interior of the disc and applying energy to the tissue surrounding the opening to substantially close the opening. Claim 15 also includes the steps of removing at least a portion of the nucleus pulposus to create a space within the annulus fibrosis, lining the space with a liner and filling the space with a fill material. Claim 27 adds to claim 15 the limitation of using some of he nucleus pulposus removed from the disc as fill material. Claims 1-33 are summarized below with references to the drawings shown in the parentheses.

Claim 1 reads as follows:

> "1. A method for closing and opening extending through annulus fibrosis into an interior of a spinal disc, the method comprising:
> creating an opening through the annulus fibrosis into the interior of the disc;
> performing a procedure within the interior of the disc; and
> applying energy to tissue surrounding the opening to substantially close the opening."

This method is illustrated, for example, in Figs. 8A-8C. As described in paragraph 93, the opening 95 is created in the annulus fibrosis 92 and opening 95 communicates with the interior region 93 which contain the nucleus pulposus. As disclosed in paragraph 94, one or more therapeutic agents may then be introduced through opening 95 into the interior region 93. As

disclosed in paragraph 96, energy may then be applied to the annulus fibrosis tissue surrounding the passage to close the passage.

Claim 15 recites the aforementioned step of creating an opening in the annulus fibrosis, and also includes the steps of removing at least a portion of the nucleus pulposus (93) to create a space (96), lining the space (96) with a substantially non-porous bioabsorbable liner material (12) and filling the space with a fill material as shown in Fig. 2G. Deployment of the liner is illustrated in Figs. 2F-2I, 3B-3D and 5. This deployment is described in paragraphs 47, 61, 63, 75 and 76.

Removal of the nucleus pulposus material as recited in claims 2 and 15 is illustrated in Fig. 2C and described in paragraph 59. Claim 5 recites the use of radio frequency energy and this is disclosed, e.g., in paragraphs 55 and 109. Claim 8 recites withdrawing the energy delivery element (e.g., 642) while delivering energy and this is disclosed in paragraph 110. Claim 13 recites the use of a syringe (616) to deliver a therapeutic agent and this is described in paragraph 106.

Claim 27 recites a method comprising the aforementioned steps of creating an opening (95), removing at least a portion of the nucleus pulposus, lining the space with a substantially non-porous material (12) and filling the space with a fill material as recited in claim 15, but adds that the fill material comprises at least some of the nucleus pulposus removed from the disc as described in paragraph 61, followed by closing the opening by applying energy to annular fibrosis tissue surrounding the opening as described in paragraph 96.

As for other dependent claims, the step of introducing a therapeutic agent into the interior of the spinal disc is disclosed in paragraph 95. The use of an extra-cellular matrix material such as submucosa as recited in claims 18, 19 and 24-26 is disclosed in paragraph 61 and in paragraph 85.

The use of concentrated growth factors derived from plasma obtained from the patient as recited in claim 28 is also disclosed in paragraph 61.

Grounds of Rejection To Be Reviewed on Appeal

Claims 1-12 have been rejected as anticipated by Lambrecht Patent No. 6,482,235.

Claims 13 and 14 have been rejected as unpatentable over Lambrecht in view of Underwood Patent No. 6,929,640.

Claims 15-18, 20, 23 and 27-29 have been rejected as unpatentable over Froning Patent No. 3,875,595 in view of Lambrecht.

Claims 19 and 24-26 have been rejected as unpatentable over Froning in view of Lambrecht and Carr Patent No. 5,733,337.

Claim 22 has been rejected as unpatentable over Froning in view of Lambrecht and Felt Patent No. 6,140,452.

Claims 30-33 have been rejected as unpatentable over Froning in view of Lambrecht and Michelson Patent No. 4,968,298.

Argument

Claims 1-12

The Examiner's rejection of claims 1-12 states that Lambrecht discloses "creating an opening through the annulus fibrosis into the interior of the disc." This is not true. The Examiner refers to Fig. 19 of Lambrecht as support for his position, but it is clear that the Examiner has things backwards. As shown in Fig. 16A and as disclosed at column 16, lines 56-59 of Lambrecht, the opening in the annulus fibrosis is **not** created by some outside force, but rather is a **pre-existing**

defect in the annulus fibrosis which has allowed the nucleus pulposus to leak through the annulus fibrosis into space outside the disc.

Lambrecht then proposes to treat this condition by introducing a "barrier" 12 into the interior of the annulus fibrosis which barrier is to be sealed to the nucleus pulposus on the internal side of the defect and thereby block further leakage of the opening in the annulus fibrosis which, as shown in Figs. 21A, 22A, 23A, 23B, 24A, 25, 26 and 27, for example, is **never closed**. Thus, Lambrecht does not disclose either creating an opening in the annulus fibrosis nor does it disclose closing an opening in the annulus fibrosis. What it does disclose is creating an interior barrier which **blocks** the opening in the annulus fibrosis without closing it. Since Lambrecht does not close the opening in the annulus fibrosis, it is not possible that he uses energy, or anything else, to close the opening. Rather, as disclosed at column 20, lines 9-49, the purpose of the energy delivery in Lambrecht is to attach the barrier 12 to the nucleus pulposus 20 and to the inner wall of the annulus fibrosis 10. Thus, Lambrecht is far afield from the recited method and cannot be considered to anticipate or in any other way render

claims 1-12 unpatentable.

Claim 13 and 14

Claims 13 and 14 have been rejected over Lambrecht in view of Underwood, with Underwood being relied upon for its disclosure of the use of a syringe to inject a therapeutic agent. However, these references are directed to completely different procedures which are essentially the antithesis of each other. Unlike Lambrecht, which is directed to preventing the loss of nucleus pulposus material, Underwood is directed to using energy ablation to **remove** nucleus pulposus

material. Underwood contains no disclosure of using energy to close an opening in the annulus fibrosis and is using energy for a totally different purpose.

In addition, Applicant can find no disclosure of the use of a syringe in Underwood, but this is beside the point. What is important is that it is not rationally possible to combine Underwood with Lambrecht. If this were done, the removal of nucleus pulposus material as taught in Underwood would undermine the use of the barrier of Lambrecht which is intended to prevent the loss of nucleus pulposus material.

Claims 15-18, 20, 23 and 27-29

The Examiner's characterization of Froning Patent No. 3,875,595 in numbered paragraph 6 of the final rejection dated May 25, 2007 is generally accurate. However, the Examiner's characterization of the Lambrecht patent is, both for the reasons stated above and additional reasons, seriously inaccurate. The Examiner recognizes that Froning does not disclose:

1. A bioabsorbable liner.
2. The use of energy to close the opening in the annulus fibrosis.
3. The use of the nucleus pulposus removed from the disc as the fill material used to fill the liner.

As discussed above, there is absolutely no disclosure of creating or closing an opening in the annulus fibrosis of a disc in Lambrecht. Lambrecht merely blocks a pre-existing opening with an internally-located barrier 12 and applies energy to adhere the barrier to the internal remaining nucleus pulposus and the inner wall of the annular fibrosis.

With regard to the use of the patient's nucleus pulposus which has been removed from the disc to fill the liner as recited in claim 16, the Examiner's characterization of Lambrecht as teaching

"the use of the nucleus pulposus within a defect (column 21, line 38)", is inaccurate. This disclosure in Lambrecht simply recognizes that there is nucleus pulposus within the annular fibrosis of the disc being treated. It says absolutely nothing about removing any of that nucleus pulposus nor does it say anything about using nucleus pulposus from any source to fill a space within the annulus fibrosis, much less that of the patent. Thus, this mischaracterization of Lambrecht renders reliance upon it fatally defective.

Lambrecht does disclose the use of resorbable materials at column 11, lines 38-41, **but not** for a liner or anything comparable to a liner. Rather, this disclosure relates to **anchors** such as elements 1 and 2 shown in Figs. 2A and 2B of Lambrecht. Thus, the Examiner's rejection with regard to this element of the claims is nothing more than a patch work of teachings which can only be prompted by the disclosure and claims of the present application. As such, the rejection is erroneous and should be reversed.

With regard to claim 17, the Examiner asserts, with absolutely no support, that "it would have been obvious to one of ordinary skill in the art to use the nucleus pulposus from the same patient in order to avoid homologous reactions." This is, of course, a misuse use of the word "homologous", but Applicant speculates that the Examiner had in mind biological rejection by reason of an immune response. However, given the fact that Froning discloses the use of a liner, which will permanently separate the fill material from the surrounding tissue, Froning would have no concern about immune response rejections and therefore contains no disclosure with regard to the biological or physiological properties of the fill material. Thus, as in the case of claim 16, the rejection of claim 17 is based on improper reconstruction of the prior art in an erroneous effort to meet the terms of claim 17.

With regard to claims 18 and 28, the Examiner's mistaken basis for rejecting claim 17 is extended by, first, erroneously adopting the premise that there is something in the prior art that discloses the use of nucleus pulposus from the same patient as fill material and then, second, recharacterizing the nucleus pulposus as "extra-cellular matrix material". As disclosed in paragraph 85, nucleus pulposus is not an extra-cellular matrix material. The rejection is erroneous because its premises are erroneous and, as will be seen, it is inconsistent with the rejection of claims 19 and 24-26.

The rejection of claim 20 falls into the same category as the rejection of claims 18 and 28. This rejection merely states the fact that nucleus pulposus from the same patient comprises an autologous material but such a statement does nothing to cure the defects in rejections of claims 17, 18 and 28 upon which the rejection of claim 20 is based.

The rejection of claim 21 which is directed to the use of a concentrated growth factor derived from centrifuged plasma of the patient, is based on the Examiner's assertion that it is the use of a "known material on the basis of its suitability". This assertion is completely unsupported. This lack of any support makes it plain that there is no sound basis for rejecting the claim. All that is offered is the arbitrary statement that such material is known to be suitable for the recited use.

Since the rejections of claims 17, 18, 20, 21 and 28 are based on no identifiable support, such rejections are based on asserted knowledge held by the Examiner. Thus, 37 CFR 1.104(d)(2), which provides that "when a rejection...is based on facts within the personal knowledge of an employee of the Office," the Applicant is entitled to request the affidavit of such an employee, is applicable here. Applicant requests an affidavit which contains support for these rejections which are apparently based on the personal knowledge of the Examiner.

Claims 19 and 24-26

These claims recite the use of an extra-cellular matrix material which can comprise at least one of intestinal submucosa, stomach submucosa or bladder submucosa and have been rejected over Froning in view of Lambrecht and Carr Patent No. 5,733,337. The Examiner has, of course, shifted gears in making this rejection as can be seen by comparing the rejection of claims 18 and 28 with the present rejection. Claims 18 and 28 were rejected on the erroneous basis that the nucleus pulposus from the patient was a "naturally occurring extra-cellular matrix material", but the Examiner in rejecting claims 19 and 24-26 relies upon Carr for its disclosure of such submucosa materials. More important than the Examiner's inconsistency is the fact that the Carr disclosure does nothing to remedy the deficiencies in the combination of Froning and Lambrecht. Furthermore, the choice of the material of Carr as a fill material is not suggested in any way in the prior art nor is there any basis in the record for concluding that it would be obvious to one of ordinary skill in the art.

Claim 22

Claim 22 has been rejected as unpatentable over Froning in view of Lambrecht and Felt Patent No. 6,140,452. Felt does disclose a filler material comprising a polymer for filling a balloon which may be used as a prosthesis. However, Felt does not cure any of the deficiencies in the combination of Froning and Lambrecht which have previously been discussed. These deficiencies include the facts that Lambrecht does not disclose creating or closing an opening in the annulus fibrosis, much less applying energy to the tissue surrounding such an opening to close it. Thus, this rejection is in error and should be reversed.

Claims 30-33

Claims 30-33 have been rejected as unpatentable over Froning in view of Lambrecht and Michelson Patent No, 4,968,298. This combination of references is completely untenable. Claims 30-33 are directed to the disclosure which appears in paragraphs 65 and 66 of the present application and which is an alternate procedure in which some of the fill material is introduced before introduction of the liner. There is absolutely no suggestion of such a procedure in Froning or Lambrecht and the Michelson patent is far afield. The Michelson device is nothing more than a suction irrigation device for use following a conventional discectomy according to which debris is removed from the space in which the discectomy is performed. The irrigation fluid of Michelson is aspirated to remove it from the discectomy space. This is the direct antithesis of the invention of claims 30-33 in which fill material is introduced into the cavity 96 in the annulus fibrosis 92 prior to introduction of the liner 12. The irrigation fluid of Michelson, which is removed from the space in which the discectomy is performed, is the exact opposite of the recited deployment of a fill material. Thus, Michelson cannot be properly combined with Lambrecht or Froning and, even if such a combination were permissible, it would not result in the invention claimed in claims 30-33. Thus, this rejection is in error and should be reversed.

Conclusion

The recurring theme which defeats the attempted rejection of claims 1-33 in this application is the erroneous characterization of Lambrecht as disclosing:

1. Creating an opening in the annulus fibrosis.

2. Closing an opening in the annulus fibrosis.

3. Using energy applied to the tissue surrounding the opening in the annulus fibrosis to close it.

This fundamental defect is then compounded by the attempts to combine Lambrecht with other references in an effort to reconstruct the invention recited in the appealed claims. These attempted combinations are fatally flawed for the reasons set forth above. Thus, it is respectfully submitted that the rejections of claims 1-33 should be reversed.

Request for Oral Hearing

Applicant hereby repeats his request that an Oral Hearing be scheduled in this application.

Fees

The Commissioner is authorized to charge Orrick's Deposit Account No. **15-0665** for any fees required and credit any overpayments to said Deposit Account No. **15-0665**.

Respectfully submitted,

Orrick, Herrington & Sutcliffe, LLP

Dated: October 23, 2007:

By: _____
James W. Geriak, Reg. No. 20, 233

ORRICK, HERRINGTON & SUTCLIFFE LLP
4 Park Plaza, Suite 1600
Irvine, CA 92614-2558
Telephone: 949/567-6700
Facsimile: 949/567-6710

APPENDIX

1. A method for closing an opening extending through annulus fibrosis into an interior of a spinal disc, the method comprising:

creating an opening through the annulus fibrosis into the interior of the disc;

performing a procedure within the interior of the disc; and

applying energy to tissue surrounding the opening to substantially close the opening.

2. The method of claim 1, wherein the step of performing a procedure comprises removing at least a portion of the nucleus pulposus material from the interior of the spinal disc.

3. The method of claim 1, wherein the step of performing a procedure comprises introducing an implant within the interior of the spinal disc.

4. The method of claim 1, wherein the step of performing a procedure comprises introducing a therapeutic agent into the interior of the spinal disc.

5. The method of claim 1, wherein the step of applying energy comprises applying radio frequency energy.

6. The method of claim 1, wherein the step of performing a procedure comprises introducing a distal portion of an elongate member into the interior of the disc.

7. The method of claim 6, wherein the step of applying energy comprises:

disposing an energy element on the distal portion of the elongate member within the opening; and

activating the energy element within the opening.

8. The method of claim 7, further comprising withdrawing the distal portion of the elongate member through the opening while the energy element is activated.

9. The method of claim 6, wherein the step of performing a procedure comprises:

inserting a distal end of a needle through tissue to a predetermined location within a patient's body; and

delivering a therapeutic agent through a lumen of the needle to the predetermined location.

10. The method of claim 9, wherein the step of applying energy comprises:

inserting an energy element into the lumen until an electrode on a distal tip of the energy element extends beyond the distal end of the needle; and

delivering electrical energy from a source of electrical energy via the electrode to tissue surrounding the electrode to substantially close the passage.

11. The method of claim 10, wherein the step of inserting an elongate element into the lumen comprises connecting a handle member to a proximal end of the needle, the elongate element extending from a distal end of the handle member.

12. The method of claim 11, wherein:

the needle comprises an electrically conductive material, and the elongate element comprises an electrically insulated outer surface that extends through the needle; and

the handle member comprises an electrically conductive region that is coupled to the needle when the handle member is connected to the needle, the conductive region being coupled to the source of electrical energy.

13. The method of claim 12, wherein the step of delivering a therapeutic agent comprises injecting the therapeutic agent through the lumen from a syringe connected to the proximal end of the needle.

14. The method of claim 13, further comprising disconnecting the syringe from the proximal end of the needle before connecting the handle member to the proximal end.

15. A method for treating a spinal disc of a patient, the spinal disc comprising annulus fibrosis and nucleus pulposus with an anterior region defined by the annulus fibrosis, the method comprising:

removing at least a portion of the nucleus pulposus material from the interior region to define a space, wherein the step of removing comprises creating an opening in the annulus fibrosis to access the interior region of the annulus fibrosis;

lining the space with a substantially nonporous, bioabsorbable liner material;

filling the space with a fill material sufficient to cause the liner material to expand to substantially engage tissue surrounding the space; and

closing the opening after filling the space with fill material, wherein the closing step comprises applying energy to annulus fibrosis tissue surrounding the opening.

16. The method of claim 15, wherein the fill material comprises nucleus pulposus.

17. The method of claim 16, wherein the nucleus pulposus used to fill the space comprises nucleus pulposus removed from the disc.

18. The method of claim 15, wherein the fill material comprises a naturally occurring extra-cellular matrix.

19. The method of claim 18, wherein the extra-cellular matrix material comprises at least one of intestinal submucosa, stomach submucosa, or bladder submucosa.

20. The method of claim 15, wherein the fill material comprises an autologous therapeutic agent.

21. The method of claim 15, wherein the autologous therapeutic agent comprises a concentrated growth factor derived from centrifuged plasma of the patient.

22. The method of claim 15, wherein the space is filled with a material comprising interpenetrating polymer network (IPN) material.

23. The method of claim 15, wherein the liner material comprises a substantially nonporous, bioabsorbable bladder, wherein the step of lining the space comprises introducing the bladder within the space, and wherein the step of filling the space comprises filling the bladder with a fill material sufficient to cause the bladder to expand to substantially occupy the space.

24. The method of claim 23, wherein the bladder comprises an extra-cellular matrix material.

25. The method of claim 24, wherein the extra-cellular matrix material comprises at least one of intestinal submucosa, stomach submucosa, or bladder submucosa.

26. The method of claim 15, wherein the liner material comprises a sheet of naturally occurring extra-cellular matrix material.

27. A method for treating a spinal disc of a patient, the spinal disc comprising annulus fibrosis and nucleus pulposus within an interior region defined by the annulus fibrosis, the method comprising:

removing at least a portion of the nucleus pulposus material from the interior region to define a space, wherein the step of removing the nucleus pulposus comprises creating an opening in the annulus fibrosis to access the interior region of the annulus fibrosis;

lining the space with a substantially nonporous liner material;

filling the space with a fill material sufficient to cause the liner material to expand to substantially engage tissue surrounding the space, the fill material comprising at least some of the nucleus removed from the disc; and

closing the opening after filling the space with fill material, wherein the closing step comprises applying energy to annular fibrosis tissue surrounding the opening.

28. The method of claim 27, wherein the fill material further comprises at least one of naturally occurring extra-cellular matrix material, saline, a pharmaceutical, an autologous therapeutic agent, a concentrated growth factor derived from centrifuged plasma of the patient, or genetic material.

29. The method of claim 27, wherein the step of lining the space comprises introducing a sheet of substantially nonporous, bioabsorbable material into the space.

30. The method of claim 27, further comprising introducing a flowable fill material into the interior region before introducing the lining the interior region.

31. The method of claim 30, wherein the flowable fill material comprises naturally occurring extra-cellular matrix material.

32. The method of claim 31, wherein the flowable fill material comprises a slurry further comprising at least one of saline, an antibiotic, a steroid, and an non-steroidal anti-inflammatory drug.

33. The method of claim 30, wherein the flowable fill material comprises an autologous therapeutic agent.